PATENT COOPERATION TREATY

PCT

'D 16 NOV 2004
WIPO PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Rec'd PCT/PTO 09 FEB 2005

Applicant's or agent's file reference 16579	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/CA 03/01180	International filing date *(day/month/year)* 11.08.2003	Priority date *(day/month/year)* 09.08.2002
International Patent Classification (IPC) or both national classification and IPC C08F220/54		
Applicant OTTAWA HEALTH RESEARCH INSTITUTE et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09.03.2004	15.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Clement, S Telephone No. +49 89 2399-8512

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA 03/01180

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-49 as originally filed

Claims, Numbers

1-50 as originally filed

Drawings, Sheets

1/20-20/20 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 51-110

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☒ the claims, or said claims Nos. 51-110 are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

☒ not complied with for the following reasons:

see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-50 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-50
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-50
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-50
	No:	Claims	

2. Citations and explanations

see separate sheet

Ad Section III:

An ocular implant comprising any synthetic polymer not defined goes beyond the content as originally filed (claims 51-64 and 65-80). An ocular implant comprising a lens body not defined goes beyond the content as originally filed (claim 81-110).

Thus, claims 51-110 do not fulfil the requirements of Art. 34 (2) (b) PCT.

Ad Section IV:

The occular implant according to claims 51 to 110 and the terpolymer according to claim 1 are not so linked as to form a single general inventive concept.

Therefore, claims 1 to 110 do not fulfil the requirements of unity (Rule 13.1 PCT).

Ad Section V:

Due to the objections under sections III and IV, the examination on novelty, inventive step and industrial applicability is based on claims 1-50:

Novelty

EP-A-0 496 472 describes succinimide-containing polymers having recurring units derived from a) one or more ethylenically unsaturated oleophilic monomers (e.g. HEMA), b) one or more ethylenically unsaturated monomers having succinimidoxycarbonyl group (N-acryloyloxysuccinimide) and optionally c) one or more hydrophilic ethylenically unsaturated monomers (N-isopropylacrylamide). The copolymers are used in diagnostic methods and analytical elements (claims, page 2, 1. paragraph, page 4, lines 8-27). EP'472 neither discloses the selected terpolymer as claimed nor the molecular weight as claimed.

In WO 92/20721 (abstract) an UV-absorbent vinyl-resin is obtained by conducting the polymerisation of a monomer mixture containing a N-alkyl substituted (meth)acrylamide monomer and a monomer bearing a salt-forming group. The resin can be blended with a cosmetic base. Novelty is given.

US 2001/0003126 discloses a composition comprising a first synthetic polymer having nucleophilic groups (e.g. a synthetic polypeptide containing primary amino groups) and a second synthetic polymer having electrophilic groups (a hydrophobic polymer containing succinimidyl groups). The nucleophilic and electrophilic groups are capable of reacting to from covalent bonds between the synthetic polymers which result in formation of a three-dimensional matrix (claims). US'126 does not disclose the synthetic terpolymer as claimed. The composition may further comprise other components (e.g. proteins) and may be used for ophthalmic applications.

US-A-6,103,528 refers to gelling cell culture medium useful for forming a three dimensional matrix for cess culture in vitro, the gelling cell culture comprising a linear random copolymer (Mw > 12,000) of N,N-dialkyl substituted (meth)acrylamide monomer and a hydrophilic comonomer (e.g. 2-ethyl (meth) acrylate, acrylic acid) (claims, column 5, lines 13 to 32). US'528 does not disclose the terpolymer as claimed.

EP-A-0 230 898 discloses polyvinyl polymers (e.g. poly(6-(4-nitrobiphenyloxy)hexyl methacrylate) exhibiting nonlinear optical response. Novelty is given.

DE-A-36 26 160 discloses glue for paper on the basis of terpolymers of (meth)acrylamide, N-vinylimidazoline and N-vinylimidazole (K-value is 70 to 250). Novelty is given.

WO 01/32730 discloses an implantable biological device capable of encapsulating biologically active moieties (e.g. tissue), said device comprising an amphiphilic network membrane (M_n = 2,000 to 15,000 g/mol) comprising the reaction product of:
a) a hyrdophilic crosslinking agent and
b) hydrophilic comonomers;
a) is a (meth)acrylic acid (capping *one* arm of the three-arm telechelic polyisobutylene) which is derivatised to contain two pendant crosslinkable moieties (two (meth)acrylic acid ester groups of the entire residue of the three-arm telechelic PIB);
b) may be DMAm (claims; page 22, 1. paragraph). The pendant crosslinking groups do not contain free (meth) acrylic acid groups that are reactive with primary amines. Thus, novelty is given.

WO 93/10201 deals with a pressure-sensitive adhesive composition comprising a

copolymer of N-vinyl-2-pyrrolidone monomer and a comonomer selected from N,N-dimethylacrylamide, HEMA, (meth)acrylic acid, acrylamide, vinyl acetate and AMPS (claim 7). WO'201 does not disclose a terpolymer.

US-A-6,030,634 describes a thermally responsive gel composition comprising
a thermosensitive polymer matrix comprising
a) a poly(n-isopropylacrylamide) modified by copolymerization with a monomer selected from (meth)acrylate, (meth)acrylic acid, (meth)acrylamide, vinyl acetate and styrene and
b) an interpenetrating hydrophilic polymer network comprising a protein.
The gel composition is used for repairing damaged tissues (claims). US'634 does not disclose the terpolymer as claimed, as it does not use the carboxylic acid comonomer derivatised to contain pendant crosslinkable moiety that are reactive with primary amines.

Inventive Step

None of the documents cited in the international search report suggests the terpolymer according to claim 1 in order to provide a biosynthetic matrix as a scaffold for tissue regeneration, for replacement of damaged or removed tissue in an animal or for coating surgical implants.

Thus, claims 1 to 50 fulfil the requirements of Art. 33 (3) PCT.

Industrial applicability

Claims 1 to 50 fulfil the requirements of Art. 33 (4) PCT).